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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,122	11/13/2001	Ronald L. Ream	112703-202	1413

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Robert M. Barrett
Bell, Boyd & Lloyd LLC
P.O. Box 1135
Chicago, IL 60690-1135

[REDACTED] EXAMINER

TRAN, SUSAN T

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1615

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/992,122	REAM ET AL.	
	Examiner	Art Unit	
	Susan Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-46 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-23 and 33-46 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 08/20/03 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Receipt is acknowledged of applicant's Information Disclosure Statement filed 12/07/01 and 07/15/02, Response to Notice to file Corrected Application and Drawings filed 08/02/02.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to method for delivering a medicament to an individual, classified in class 426, subclass 5.
- II. Claims 8-23, drawn to a product comprising chewable water insoluble center and a coating, classified in class 424, subclass 440.
- III. Claims 24-27, drawn to a method for reducing the amount of agent necessary to achieve an effect in an individual, classified in class 424, subclass 48.
- IV. Claims 28-32, drawn to method of enhancing an individual's performance, classified in class 424, subclass 48.
- V. Claims 33-41, drawn to method of delivering a medicament, classified in class 426, subclass 5.
- VI. Claims 42-46, drawn to method of manufacturing a medicament, classified in class 424, subclass 48.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, III, IV, V and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group II does not have to be delivery by the process of Groups I, III, IV, and V.

Inventions Group III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of Group III does not practice require the performance from individual, e.g., athletic, cognitive, and alertness.

Inventions Group I and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the method of I does not practice require the present of taste masking agent.

Inventions Group II and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of Group II can be made using

different process. The process of Group VI obtained a chewing gum product, which does not require the present of taste masking agent.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-23, and 33-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16, 18-24, 26-30, and 32-34 of co-pending Application No. 10/206,492 ('492). Although the conflicting claims are not identical, they are not patentably distinct from each other because '492 claims a method of delivering a medicament to an individual containing a chewing product comprising a gum center; and a coating layer containing medicament and optionally sufficient amount of masking agent substantially surrounds the center, wherein the coating comprising at least 50% by weight of the chewing gum product. Medicament is found in claims 6, 10, 18, and 32. The coating includes a high-intensity sweetener is found in claim 2. The water-insoluble gum base is found in claims 5, 15,

and 29. The coating layer does not contain shellac is found in claims 8, 16, 26. Therefore, those of ordinary skill would expect a similar method for delivering a chewing product results from the use of the present invention given the claims of '492. There are no unusual and/or unexpected results that would rebut *prima facie* obviousness. As such, the instant claims would have been obvious given the claims of '492, which set out a similar method of delivering medicament using the same materials and conditions as claimed herein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 8-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,355,265 ('265). Although the conflicting claims are not identical, they are not patentably distinct from each other because '265 claims a chewing gum comprising a gum center comprising a water soluble *portion* and a water insoluble *portion*; and a coating comprising a medicament that surrounds the gum center, the coating comprising at least 50% by weight of the chewing gum product. Medicament is found in claim 2. Coating further includes taste masking agent is found in claims 3 and 4. The percent amount of taste masking agent present in the coating is found in claim 5. The percent amount of high-intensity sweetener is found in claim 6. The water-insoluble gum base is found in claim 7. The coating layer does not contain shellac is found in claim 8. The comprising language in claim 8 of the present invention allows the present of water-soluble *portion* in '265. The phrase "water insoluble *portion*" in claim 1 of '265

allows “elastomers, resins, fats, oils, softeners, and inorganic fillers” in claim 15 of the present invention. Therefore, those of ordinary skill would expect a similar chewing product results from the use of the present invention given the claims of ‘265. There are no unusual and/or unexpected results which would rebut *prima facie* obviousness. As such, the instant claims would have been obvious given the claims of ‘265, which set out a similar chewable product using the same components as claimed herein.

Claims 42-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6, and 7 of U.S. Patent No. 6,465,003 ('003). Although the conflicting claims are not identical, they are not patentably distinct from each other because '003 claims a method of manufacturing a medicament containing product comprising the steps of preparing a gum center having a water soluble *portion* and a water insoluble *portion*; and coating the center by placing alternating layers of a powder and a syrup containing medicament on the center to create a coated product, wherein the coating comprising at least 50% by weight of the chewing gum product. Medicament is found in claim 4. The coating includes a high-intensity sweetener is found in claim 3. The water-insoluble gum base is found in claim 2. The coating layer does not contain shellac is found in claim 7. The phrase “water insoluble *portion*” in claim 1 of '003 allows “water insoluble *components*” in claim 42 of the present invention. Therefore, those of ordinary skill would expect a similar chewing product results from the use of the present invention given the claims of '003. There are no unusual and/or unexpected results which would rebut *prima facie* obviousness. As such, the instant claims would have been obvious given the claims of '003, which set

out a similar method of manufacturing medicament using the same materials and conditions as claimed herein.

For the convenience of the applicant, the MPEP§2111.03 states “the transitional term “comprising”, which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948)(“comprising” leaves “*the claim open for the inclusion of unspecified ingredients even in major amounts*””).

In reviewing the application, it was noted that several co-pending applications appear to be directed to the same subject matter. In particular, 09/759,561 (has been issued, not yet printed); 10/044,113; and 10/206,492. All appear to deal with chewing product and method for delivering/manufacturing/enhancing/reducing a medicament to an individual comprising a chewing gum that includes a gum base center, and a coating-containing medicament. Applicant is requested to forward copy of the claims in all co-pending applications but the 10/206,492 application (which is used herein for an obviousness-type double patenting rejection) in order to resolve possible double patenting issues.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



THURMAN K. PAGE
SUPERVISOR PATENT EXAMINER
TECHNOLOGY CENTER 1600